

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

In re Innocoll Holdings Public Limited
Company Securities Litigation

CLASS ACTION

This Document Relates To:
All Actions

Master File: 2:17-cv-00341-GEKP

**AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

Lead Plaintiffs Russel Bleiler, Ashok Chainani, JianMin Huang, and Carl Bayney, and Named Plaintiff Gaurangkumar Patel (“Plaintiffs”), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants (defined below), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants’ public statements, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Innocoll Holdings Public Limited Company (“Innocoll” or the “Company”), discussions with former Innocoll employees and other persons with knowledge, consultation with an expert, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION AND OVERVIEW

1. This is a securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased or otherwise acquired the publicly traded securities of Innocoll between July 25, 2014, and December 29, 2016, both dates inclusive, (the “Class Period”), including in public offerings closing on or around July 25, 2014, April 23, 2015, and June 17, 2016, seeking to recover damages caused by Defendants’ violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. Innocoll is a small biotechnology company formed to develop and commercialize medical products based on its patented collagen technologies used in medical sponges, films,

powders and other structures. Innocoll's collagen products are designed to be inserted into the human body and then absorbed into the body – rendering surgery to remove the products unnecessary.

3. Innocoll was established in 1997. While it has commercialized certain of these products since, they have not been successful; Innocoll has consistently incurred operating losses in manufacturing and selling the products. In fact, by 2014, Innocoll had incurred an accumulated deficit of almost €100 million.

4. Innocoll conducted its IPO in July 2014. However, investors were relatively uninterested in Innocoll's shares and the IPO raised less cash than Innocoll had sought. A later offering in 2015 did not even raise enough money to take Innocoll's products through the filing of the New Drug Application process, which Innocoll claimed would occur in late 2016. And a third offering in 2016 had to be significantly downsized mere days after it was announced.

5. Innocoll's inability to raise enough cash to fund its operations left it perpetually cash-strapped and led it to cut corners.

6. Innocoll seeks to sell its products in the U.S. Before selling any drug or medical device in the U.S., a company must seek approval from the FDA. Medical devices are defined as instruments or the like that “do[] not achieve [their] primary intended purposes through chemical action within or on the body.”

7. Whether a manufacturer aims to sell a product as a drug or a device, however, the manufacturer must obtain the FDA's approval. Drugs are typically approved following three phases of clinical trials, dubbed Phase I, Phase II, and Phase III, the last of which aims to show that the drug is safe and effective with statistical confidence. Devices have more heterogeneous

routes to approval, but the manufacturer must demonstrate to the FDA reasonable assurances of their safety and effectiveness.

8. Innocoll's lead product XaraColl is a drug/device combination made up of Innocoll's collagen sponge and a local anesthetic, bupivacaine, which was discovered in the 1950's and has been in continuous use as an anesthetic for decades. XaraColl is inserted into the body during surgery, and slowly releases bupivacaine, addressing post-operative pain. XaraColl's collagen component is then absorbed into the body.

9. Since its first use as a medical product, collagen has consistently been regulated by the FDA as a "*device*". Indeed, Innocoll itself, on eight separate occasions, sought and obtained FDA approval for use of its collagen technologies *as devices*. And Innocoll's Chief Medical Officer ("CMO") and regulatory head each internally referred to XaraColl as a "*device*".

10. Products that have both drug and device components are called drug/device combination products. A manufacturer seeking approval to market such products must obtain approval of both the drug and the device components. In XaraColl's case, this means in addition to the drug trials, Innocoll was required to run a pharmacokinetic study and various non-clinical studies to establish that the collagen sponge was safe and effective as used in XaraColl.

11. Yet unbeknownst to investors, when Innocoll ran clinical trials for XaraColl, it only ran trials for its drug components – not its device components. That left Innocoll's application fatally flawed and unapprovable.

12. It is the responsibility of the company submitting an application – dubbed a "sponsor" in FDA nomenclature – to ensure that the application correctly characterizes the product as a device, a drug, or a drug/device combination, and provides all studies necessary for approval.

13. The FDA offers companies who seek approval of a product – referred to as “sponsors” in FDA nomenclature – the opportunity to hold formal meetings with the FDA to discuss and determine such questions. It has even established an Office of Combination Products (OCP) and instructs sponsors of combination products to seek out the OCP to gather advice on how best to proceed before entering the approval process.

14. Defendants repeatedly informed investors, beginning with the IPO and continuing through to the very end of the Class Period, that Innocoll had held two formal meetings with the FDA. Defendants misleadingly suggested that the FDA had “approved” and “deemed [] acceptable” XaraColl’s pathway to FDA approval at these meetings. Defendants further represented that there were “no gating issues” to approval, other than Phase 3 clinical trials for XaraColl, and that in their opinion “approval is [] not in question.” Innocoll then filed its New Drug Application (“NDA”) for XaraColl in October 2016.

15. But the FDA had done no such thing. In fact, after the close of the Class Period, Innocoll admitted to an analyst that it had never even broached the subject of classification as a drug/device combination with the FDA.

16. Because Innocoll had not conducted the studies necessary for approval of the device components of XaraColl and the FDA had not waived Innocoll’s failure to do so, it was substantially certain that XaraColl would not be approved.

17. On December 29, 2016, Innocoll announced that it had received a refusal to file letter from the FDA for its XaraColl NDA. A refusal to file letter is not a denial of an NDA; rather, it is a determination made in extraordinarily rare circumstances that the application is so deficient that a substantive review is a waste of time. According to Innocoll, the chief reason the FDA

provided for its refusal to accept the XaraColl NDA filing were that XaraColl was not a drug, but a drug/device combination – exactly what Innocoll concealed from and misstated to investors.

18. On December 30, Innocoll's stock price fell over 61%, damaging investors.

JURISDICTION AND VENUE

19. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

21. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)) as the Company's U.S. headquarters are located in this judicial district.

22. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

23. Plaintiffs Russel Bleiler, Ashok Chainani, JianMin Huang, and Carl Bayney, as set forth in their PSLRA Certifications which were previously filed and are incorporated by reference

herein, purchased Innocoll securities at artificially inflated prices during the Class Period and were damaged thereby.

24. Named Plaintiff Gaurangkumar Patel, as forth in his PSLRA Certification which is attached as an exhibit and incorporated by reference herein, purchased Innocoll securities at artificially inflated prices during the Class Period and was damaged thereby.

25. Defendant Innocoll is a global specialty pharmaceutical company with late stage development programs built around its proprietary collagen technology. Throughout the Class Period, its principal executive offices were located in Monksland, Athlone, Co. Roscommon, Ireland, and its U.S. headquarters were located in this District at 3803 West Chester Pike, Newtown Square, PA 19073.

26. Innocoll began the Class Period as Innocoll AG, a German Company. Then, on March 16, 2016, Innocoll AG was “merged” into Innocoll Holdings plc, in a transaction that changed Innocoll’s domicile to Ireland but had no substantial effect on its operations or ownership. Under SEC rules, Innocoll Holdings plc was deemed a successor to Innocoll AG. Innocoll Holdings plc kept the same trading symbol as Innocoll AG, and also inherited Innocoll AG’s active shelf registration statement. Before March 16, 2016, Innocoll AG’s American Depositary Shares (“ADSs”) were traded on the NASDAQ under ticker INNL. After March 16, 2016, Innocoll Holdings plc’s common shares were traded on the NASDAQ under ticker INNL.

27. Defendant Anthony P. Zook has been Innocoll’s CEO since December 8, 2014. Defendant Zook has over 30 years of experience in the pharmaceutical industry. He held several executive positions with pharmaceutical giant AstraZeneca, including President and Chief Executive Officer of its North American division accounting for more than ten billion dollars in

annual sales during his tenure. He sits on the Board of Directors of several biotechnology companies, including AltheRx, Inhibikase, and Rib-X Pharmaceuticals.

28. Defendant Dr. Lesley Russell has served as Innocoll's Chief Medical Officer ("CMO") since April 20, 2016. According to a Press Release issued by Innocoll that day, Defendant Russell "has extensive experience managing the development of pharmaceuticals and biologics across a wide range of therapeutic areas, dosage forms and formulations on a global scale." Defendant Russell served as the Chief Operating Officer and CMO of TetraLogic Pharmaceuticals, where she advanced that company's lead candidate into Phase 2 clinical trials. She has experience managing staff responsible for regulatory strategy development.

29. Defendants Zook and Russell are the "Individual Defendants."

30. Innocoll is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

31. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Innocoll under respondeat superior and agency principles.

32. Defendants Innocoll and the Individual Defendants are the "Defendants."

Background

33. One of Innocoll's main products is XaraColl, which uses bupivacaine for the treatment of postoperative pain. XaraColl is a proprietary collagen matrix that is implanted near the wound site during surgery and releases the anesthetic over time to provide sustained postsurgical pain relief, rather than injecting bupivacaine directly into the wound site to be delivered all at once in one dose. This is viewed as a superior method of pain management as it

requires lesser amounts of drugs to provide relief. The collagen matrix is bioresorbable, meaning that it dissolves by itself over time and is absorbed into the body.

34. The U.S. Food and Drug Administration (the “FDA”) is the federal government agency responsible for approval of drugs, medical devices, and drug/device combinations, including Innocoll’s products. The Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. 9 § 301 *et seq.*, governs the regulation and safety of, among other things, drugs and medical devices in the United States.

35. The FDA’s Center for Drug Evaluation and Research (“CDER”) is designated the lead Center for regulating drugs to ensure their safety and effectiveness and will generally use authorities under the drug provisions of the Act. The mission of CDER is to ensure that drugs marketed in this country are safe and effective. CDER does not test drugs, although the Center’s Office of Testing and Research does conduct limited research in the areas of drug quality, safety, and effectiveness. CDER is the largest of FDA’s six centers responsible for monitoring drugs, biologics, and medical devices.

36. In order to introduce a new drug into the U.S. market, a company submits a New Drug Application (NDA) to introduce a new drug product into the U.S. market. It is the responsibility of the company, or sponsor, seeking to market a drug to test it and submit adequate evidence to the FDA that it is safe and effective. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the sponsor’s NDA containing the data and proposed labeling.

37. An NDA must provide enough information to permit FDA reviewer to determine whether the drug is safe and effective in its proposed use(s), whether the benefits of the drug outweigh the risks, whether the proposed labeling is appropriate, and whether the manufacturing

methods are adequate to preserve the drug's strength, quality, and purity. The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.

38. The medical device counterpart to CDER is the Center for Devices and Radiological Health ("CDRH"). CDRH is designated the lead center for the FDA for regulating medical devices to ensure their safety and effectiveness. CDRH will generally use the device authorities of the Act as appropriate, for devices regulated in that Center.

39. The FDA established the Office of Combination Products ("OCP") to develop guidance and regulations governing combination products, to assign an FDA center to have primary jurisdiction for review of both combination and non-combination products where the jurisdiction is unclear or in dispute, and to ensure timely and effective premarket review of combination products by overseeing and coordinating reviews involving more than one agency center. OCP is a resource to help answer questions regarding combination products, and will do so informally or formally through answering a sponsor company's Request for Designation ("RFD"), which determines which FDA medical product center has primary jurisdiction for a combination product.

40. The FDA makes it clear that in the first instance, determining whether a product is a drug, device, or combination product is the company's responsibility. On the FDA website for medical devices, in the section for regulatory assistance, under the header titled "How to Study and Market Your Device", the FDA warns companies that:

If your product is a combination product - a medical device plus another FDA-regulated product (e.g. drug, biologics, etc.), you should contact FDA's Office of Combination Product (OCP) by e-mail []. Based on your product's primary mode of

action, OCP will tell you which FDA Center that you need to contact in order to market your product.

41. The same page indicates that “[y]ou must follow the steps below prior to marketing a medical device in the United States.”

42. A combination product is assigned to an Agency Center or alternative organizational component that will have primary jurisdiction for its premarket review and regulation. Under section 503(g)(1) of the Food and Drug Act, assignment to a center with primary jurisdiction, or a lead center, is based on a determination of the “primary mode of action” (PMOA) of the combination product, defined as the single mode of action of a combination product that provides the most important therapeutic action of the combination product. For example, if the PMOA of a device-biological combination product is attributable to the biological product, the Agency component responsible for premarket review of that biological product would have primary jurisdiction for the combination product.

43. Depending upon the type of combination product, its approval, clearance or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. The FDA may determine that two marketing applications are necessary. For example, when one of the individual constituent parts of a combination product is already approved for another use, and where the labeling of the already approved product will need to be changed to reflect its new intended use in the combination product, FDA may determine that two applications are necessary if the labeling of the already approved product is subject to legal requirements different from those that will apply to the combination product.

44. Obtaining approval of a drug typically requires three sets of clinical trials. Phase 1 trials establish that the drug is safe to be studied and establish dosage. Phase 2 trials are meant to

establish clinical efficacy. But Phase 2 trials are typically not large enough to statistically demonstrate that the drug is safe and effective. Phase 3 trials are pivotal trials. They are designed to be large enough to show that the drug is effective, safe and does not have adverse reactions. Each phase has a distinct timeline – Phase 1 typically lasts a few months, Phase 2 a few months to two years, and Phase 3 one to four years.

45. Obtaining approval for a device requires, at a minimum, a demonstration of safety and effectiveness. Devices posing low to moderate risks, such as a manual toothbrush, are referred to as Class I devices and face only general controls. Devices posing moderate to high risk, such as a non-invasive blood pressure monitor, are subject to general and special controls.

46. Because the FDA had never approved a device employing Innocoll's collagen sponge to release a drug over time, at a minimum, Innocoll was required to present clinical and nonclinical data showing the safety and effectiveness impact of the collagen sponge. 21 C.F.R. §807.87(g). The FDA required a clinical pharmacokinetic study and non-clinical toxicology and biocompatibility studies.

A new CEO promises quick results

47. Innocoll's legal predecessor was incorporated in Delaware in 1997. Since inception, Innocoll has been developing and seeking to commercialize drugs and devices that employ its proprietary collagen technologies.

48. Innocoll has had limited success. By March 31, 2014, shortly before its IPO, Innocoll had an accumulated deficit of €90.8 million, and its current liabilities exceeded its current assets by €6.9 million. Innocoll's revenues were approximately €3.5 million and €4.3 million in 2013 and 2012, respectively, while incurring operating losses of €6.9 million and €6.4 million, respectively.

49. At the time, Innocoll had two major product candidates in its pipeline: XaraColl and Cogenzia, for the treatment of diabetic foot infections.

50. As early as 2008, Innocoll knew that XaraColl had device aspects. The patent obtained for XaraColl, Number US 20080241245 A1, filed on March 28, 2008, is titled “A drug delivery device for providing local analgesia, local anesthesia or nerve blockade.” XaraColl is described as “...the *device* comprising a fibrillar collagen matrix; and at least one drug substance...being substantially homogeneously dispersed in the collagen matrix....”¹ The inventors listed on the patent include Michael Myers, Innocoll’s CEO.

51. The filing of the XaraColl patent came two years after Innocoll first filed for approval of a collagen sponge device with the FDA, for CollaGUARD.

52. Innocoll has a decade’s worth of prior experience of bringing collagen products to the FDA for approval. All these collagen products were classified as devices with the FDA. In fact, Innocoll used this long experience as a selling point to investors. For example, Charles F. Katzer, Innocoll’s Vice President, Global Supply and Procurement, touted on a November 4, 2016 conference call “Similarly so, with our experience in the extraction and purification of Type 1 collagen of over 20 years specifically in the bupivacaine collagen formulation for XARACOLL here. We have a strong stability profile exceeding most. We have the benefit of 20 years’ experience in the product. So, we have a strong database to support our CMC section in there.”

53. From 2006 through 2014, Innocoll obtained FDA approval to sell eight separate devices. All of these devices were made from collagen. Innocoll presented them as medical devices to the FDA under the following names (year submitted in parentheses): CollaGUARD (2006),

¹ All bold and italicized emphases are added.

Collieva (2008), Collagen Sponge (2010), Collexa (2010), Collacare Dental (2011), Collagen Powder (2011), Procoll (2012), and Collacare Dental (2014).

The FDA's door is open to companies seeking guidance

54. Companies that are faced with ambiguous issues in seeking approval may seek formal meetings with the FDA to answer questions they may have about drug or device approval issue. The FDA has issued guidance on the subject, titled “Formal Meetings Between the FDA and Sponsors of Applicants” (the “Meeting Guidance”).²

55. While the FDA attempts to guide companies, the Meeting Guidance makes it clear that it is ultimately up to companies to identify issues for the FDA on which they seek guidance:

- a. The company's meeting request must include among other things a brief statement of the purpose and objectives of the requested meeting, a proposed agenda (including a brief background on the issues underlying it), a list of proposed questions (including their purpose), and a list of FDA professionals (by name, if known, or discipline, if not) who are requested to attend the meeting. Meeting Guidance, at 4-5.
- b. The request “should define the specific areas of input needed from [the FDA division].” Meeting Guidance, at 5.
- c. The meeting package submitted by the company to the FDA must include among other things a brief statement summarizing the purpose of the meeting, a proposed agenda, and a list of the questions for discussion with a summary for each question to explain the need or context.

² References are to the version issued in May 2009, which was the latest official version at the time of Innocoll's End of Phase 2 and July 2015 Meetings with the FDA.

56. Companies may also seek FDA guidance informally by telephone or email.

57. Defendants' Class Period statements advised investors that Innocoll had held two meetings with the FDA. First, before the Class Period, Innocoll held an end-of-Phase 2 meeting with the FDA to discuss XaraColl's Phase 3 trials. Second, in July 2015, Innocoll held a formal meeting with the FDA to discuss XaraColl's Phase 3 trials.

Defendants were aware that XaraColl had device components

58. Sources inside Innocoll confirm that Defendants understood that XaraColl had device components that would require separate approval by the FDA.

59. Innocoll employed a Medical Affairs Consultant from July 2015 through to November 2015 (the "Medical Affairs Consultant"). The Medical Affairs Consultant's responsibilities included ensuring that XaraColl's promotional materials were medically and technically accurate. He reported directly to Innocoll's then-CMO Dr. James Tursi, until Tursi left Innocoll in September 2015. The Medical Affairs Consultant also worked closely with David Prior.

60. Tursi was CMO of Innocoll from March 2015 through September 2015. CMO is a senior officer position, and Tursi reported directly to Defendant Zook. Dr. Tursi has more than twenty years of medical experience, including four years as CMO of Auxilium Pharmaceuticals, which was acquired for \$2.6 billion.

61. David Prior was employed at Innocoll in senior positions since December 2004, and served as Executive Vice President – Clinical, Regulatory and Scientific Affairs from 2008 through the end of the Class Period. Prior was listed as one of six members of Innocoll's executive management team in its SEC filings and on its website during the Class Period.

62. The Medical Affairs Consultant reports that both Prior and Tursi specifically told him during his tenure that XaraColl was a device. Indeed, the Medical Affairs Consultant told

Plaintiffs “I was told in the U.S. that it would be considered as a device. That’s what I remember being told.

Materially False and Misleading Statements Issued During the Class Period

63. On July 24, 2014, Innocoll filed an Amended Registration (the “IPO Registration Statement”) on Form F-1/A for shares to be sold pursuant to its IPO. Michael Myers signed the IPO Registration Statement.

64. The IPO Registration Statement was declared effective on July 25, 2014.

65. Pursuant to the IPO Registration Statement, Innocoll sold 6,500,000 ADSs, with net proceeds to it of \$54.4 million, before expenses. As Innocoll admitted on its conference call to discuss its Q3 2014 earnings (the “Q3 2014 Earnings Call”), the amount was “lower than [Innocoll’s] initial target.”

66. The IPO Registration Statement provided, in relevant part:

XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours (44% reduction; $p = 0.001$), 48 hours (37% reduction; $p = 0.012$) and 72 hours (34% reduction; $p = 0.030$). In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in opioid consumption through 24 and 48 hours (44% reduction at 24 hours, $p = 0.004$, and 36% reduction at 48 hours, $p = 0.042$), and demonstrated a statistical trend in reduction in pain intensity through 24 hours ($p = 0.080$). When we apply the Silverman method, a validated statistical analysis that integrates the patient’s pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours ($p = 0.013$) and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours ($p = 0.005$ and $p = 0.039$, respectively) as well as a statistical trend through 72 hours ($p = 0.07$). ***The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, as agreed to with the FDA in our end-of-Phase 2 meeting.***

12. The IPO Registration Statement also provided:

Develop XaraColl for treatment of post-operative pain. We plan to initiate our two planned Phase 3 trials for XaraColl in the second half of 2014, *as established with the FDA at our end-of-Phase 2 meeting*.

13. The IPO Registration Statement similarly provided:

Thus we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. Following our end-of-Phase 2 meeting, *the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial*.

67. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that it had held a XaraColl Post Phase-2 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Innocoll conveyed that it had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Innocoll and its officers knew that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

68. On December 8, 2014, Defendant Zook was appointed as Innocoll's CEO.

69. Zook immediately promised investors quick results.

70. On his very first earnings call, discussing Innocoll's Q4 2014 results on March 19, 2015 (the "Q4 2014 Earnings Call"), Zook remarked that "the historical lack of financial resources that led to delays in the delivery of programs is behind us." Zook added that "Therefore, meeting

our key delivery dates is our highest priority. We should never lose sight of the value these medications can provide to patients, and therefore speed and quality matters.”

71. Indeed, Zook promised that Innocoll would (a) complete the approval process, (b) expand its manufacturing facilities, and (c) develop commercialization plans, among other things, over the next 12 months.

And there are four key deliverables over the next 12 months. *One, we have to complete our clinical programs for XaraColl and Cogenzia on time and on budget is our highest priority.* Number two, we have to complete our manufacturing expansion in time to be able to fully launch all our products to their full potential. Third, to fully evaluate our commercial options for each of our lead candidates and geographies, and finalize these plans in the second half of this year. And four, to reevaluate our existing commercial partnerships, and take the necessary steps to improve the performance our brands globally moving forward.

72. Zook continued to stress these tight deadlines in successive calls. For example, on the call to discuss Innocoll’s first quarter 2015 earnings (the “Q1 2015 Earnings Call”) held on May 14, 2015, Zook claimed that Innocoll was making “excellent progress” on its plan. On the call to discuss second quarter 2015 earnings (the “Q2 2015 Earnings Call”), Zook stressed that “we anticipate completing enrollment [on XaraColl’s Phase 3 study] before the end of the first quarter of 2016 and anticipate reporting top line data from both studies during the second quarter of 2016.” On the call to discuss third quarter 2015 earnings (the “Q3 2015 Earnings Call”), Zook stressed that “top line results will be available in the second quarter of 2016, which could lead to a regulatory submission by the close of 2015 [sic - 2016].”

73. On March 19, 2015, Innocoll filed its 20-F for the year ended December 31, 2014 (the “2014 20-F”), which was signed by Defendant Zook. Separately, Defendant Zook executed a certification under the Sarbanes-Oxley Act of 2002 (“SOX”), certifying that:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the

circumstances under which such statements were made, not misleading with respect to the period covered by this report
[...]

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; [and]
[...]
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
[]

14. The 2014 20-F provided, in relevant part:

XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours (44% reduction; $p = 0.001$), 48 hours (37% reduction; $p = 0.012$) and 72 hours (34% reduction; $p = 0.030$). In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in opioid consumption through 24 and 48 hours (44% reduction at 24 hours, $p = 0.004$, and 36% reduction at 48 hours, $p = 0.042$), and demonstrated a statistical trend in reduction in pain intensity through 24 hours ($p = 0.080$). When we apply the Silverman method, a validated statistical analysis that integrates the patient's pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours ($p = 0.013$) and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours ($p = 0.005$ and $p = 0.039$, respectively) as well as a statistical trend through 72 hours ($p = 0.07$). These results are indicative of a clear dose-related response. ***The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, as agreed to with the FDA in our end-of-Phase 2 meeting.*** [] We plan to approach the FDA to gain its approval to the change in our study protocol and, subject to this approval, plan to commence testing XaraColl in the third quarter of 2015, ***with pivotal data anticipated in early 2016. We expect to file an NDA for XaraColl in 2016.***

15. The 2014 20-F also provided:

Thus we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. Following our end-of-Phase 2 meeting, *the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial.*

74. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that they had held a XaraColl Post Phase-2 meeting with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that they had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Defendants were aware that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

75. On April 23, 2015, Innocoll filed a Registration Statement on Form F-1/A (the "F-1 Registration Statement") in connection with a secondary offering of 3,321,669 ADSs. Of these, 1,999,690 consisted of ADSs sold by Innocoll, and 1,321,979 consisted of ADSs to be sold by certain identified shareholders. The total public offering price was approximately \$29.9 million, of which Innocoll received approximately \$16.9 million, and Innocoll employees received approximately \$4.3 million. The capital raise was plainly insufficient to Innocoll's needs. In fact, as Innocoll admitted on its conference call to discuss its Q2 2014 earnings (the "Q2 2014 Earnings

Call”), taking place on August 14, 2015, the capital raise was only sufficient to fund its operations through the first half of 2016, though Innocoll projected it would file XaraColl’s NDA in the second half of 2016. Defendant Zook signed the F-1 Registration Statement.

76. The F-1 Registration Statement was declared effective on April 23, 2015.

77. The F-1 Registration Statement provided, in relevant part:

XaraColl has been studied in one Phase 1 and four completed Phase 2 clinical trials enrolling approximately 184 patients, including 103 patients in two Phase 2 trials in hernia repair at doses of 100 mg and 200 mg of bupivacaine. Results from both trials demonstrated that XaraColl reduces both pain intensity and opioid consumption with the 200 mg dose resulting in an overall greater combined effect at 48 hours. XaraColl-treated patients in the 100 mg dose trial experienced significantly less pain through 24 hours, 48 hours and 72 hours. In our subsequent 200 mg dose trial, XaraColl demonstrated a statistically significant reduction in opioid consumption through 24 and 48 hours, and demonstrated a statistical trend in reduction in pain intensity through 24 hours. When we apply the Silverman method, a validated statistical analysis that integrates the patient’s pain intensity with opioid consumption, to these results, the 100 mg dose trial demonstrated a statistically significant reduction at 24 hours and the 200 mg dose trial demonstrated a statistically significant reduction at both 24 and 48 hours as well as a statistical trend through 72 hours. These results are indicative of a clear dose-related response. The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, *as agreed to with the FDA in our end-of-Phase 2 meeting*.

78. The F-1 Registration Statement also provided:

The primary endpoint in our two planned Phase 3 trials will use this integrated Silverman method assessment of pain and opioid consumption, *as agreed to with the FDA in our end-of-Phase 2 meeting*.

79. The F-1 Registration Statement also provided:

Thus, we believe that by applying the Silverman method and integrating both pain intensity and opioid consumption into a single endpoint rather than assessing a single parameter alone, we can generate a more meaningful interpretation of trial results. *Following our end-of-Phase 2 meeting, the FDA agreed to permit us to pursue such integrated end point in our Phase 3 trial.*

80. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that they had held a XaraColl Post Phase-2 meeting

with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that they had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Defendants were aware that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

81. On October 8, 2015, Innocoll filed an Amended Registration Statement on Form F-3/A (the "F-3 Registration Statement"). Form F-3 registration statements are called shelf registration statements because they permit SEC-registered companies to register shares and place them "on the shelf" to be sold at a later time. But SEC rules provide that any future reports on Form 20-F, as well as any prospectuses, are incorporated into any Form F-3 that is declared effective. The Form F-3/A was declared effective on October 9, 2015.

82. On March 17, 2016, Innocoll filed its 20-F for the year ended December 31, 2015 (the "2015 20-F"), which was signed by Defendant Zook.

83. The 2015 20-F provided:

After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, are running both Phase 3 trials in parallel, focusing only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting*** [in July

2015]. Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. Our MATRIX Phase 3 studies are two identical randomized, placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. ***We expect to submit an NDA for XaraColl at the beginning of the fourth quarter of 2016.***

84. The 2015 20-F continued:

The FDA has reviewed the data from [XaraColl's Phase 2] study and agreed with with [sic] Innocoll's decision to proceed with the evaluation of the single 300mg dose of XaraColl in the current Phase 3 program.

85. The 2015 20-F added:

The FDA has approved [our Phase 3 study] protocol and we commenced testing XaraColl at the 300 mg dose in the third quarter of 2015, with pivotal data anticipated in the first half of 2016. We previously received topline data from our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose versus standard bupivacaine infiltration which supports the selection of a 300 mg dose of XaraColl to be tested in our MATRIX Phase 3 efficacy trials. We had initially planned to conduct our Phase 3 trials using a single, integrated endpoint, validated in pain studies, that integrates and weights the patient's pain score and use of rescue analgesia equally, known as the Silverman method so that the results can take into account a patient's choice to suffer more pain or take higher dosages of rescue analgesia. However, in accordance with recommendations that we received from the FDA in connection with our recent Type C meeting [in July 2015], we are not using an integrated endpoint in our Phase 3 trials and instead rely upon a primary endpoint of SPIDfor [sic] both trials.

We also increased the number of patients from 240 to 300 to ensure that the safety database from our studies will include no less than 500 subjects, ***as requested by the FDA.***

86. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that they had held XaraColl Post Phase-2 and July 2015 meetings with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed

that they had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Defendants were aware that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

87. Also on March 17, 2016, Innocoll held a conference call to discuss its Q4 2015 results (the "Q4 2015 Earnings Call"). On the call, an analyst specifically asked whether there was anything that Innocoll needed to do other than the Phase 3 studies to obtain approval for XaraColl:

<Analyst> Okay, great. And are there any other nonclinical things that you have to get out of the way for the XaraColl filing and safety database, any kind of manufacturing issues that you need to address, like anything else that is nonclinical related to XaraColl will have to be prepared before you file?

<Defendant Zook> ***Nothing that hasn't already been done and shared with the FDA*** so we are good to go once we get the results with these two preclinical programs before we get the green light.

88. Defendant Zook's statement was false because Innocoll had not raised the device issue with the FDA at all nor obtained any waiver of the device requirement. Defendant Zook's statement thus concealed the substantial certainty that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

89. On May 16, 2016, Innocoll filed a post-effective amendment to the Registration Statement (the "Amendment").

90. The Amendment was signed by Defendant Zook.

91. The Amendment provided:

After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, are running both Phase 3 trials in parallel, focusing only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting*** [in July 2015]. Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. Our MATRIX Phase 3 studies are two identical randomized, placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. ***We expect to submit an NDA for XaraColl at the beginning of the fourth quarter of 2016.***

92. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that they had held XaraColl Post Phase-2 and July 2015 meetings with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that they had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Defendants were aware that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

93. On May 25, 2016, Innocoll published a press release announcing the results of its XaraColl Phase 3 trials. The press release stated that the Phase 3 “Data supports on-schedule NDA filing this year.”

94. That same day, Innocoll held a conference call to discuss the XaraColl Phase 3 trial results. On the call, analysts repeatedly asked whether there were any remaining steps necessary for filing the NDA; Defendants Zook and Russell both denied that there were any:

<Analyst>: Thanks. I had a couple [of questions]. First, *can you just remind us if there are any other gating factors beyond the clinical trial to the NDA filing*, and the manufacturing hurdles, if any, that we’d need to be aware of? [...]

<Defendant Zook> Thanks. What I will do at this point, David, I’ll ask Nigel [Jones] to weigh a little bit on your third question, on the feedback we’ve received anecdotally, because he’s had the most interactions with people involved with the trials, so he can give you some sense of how they see the product, and then what other potential applications there might be.

As far as any other gate staging moment, we believe now that we’re in a good position to move forward with our NDA submission, and as we had indicated, we want to get that done this year. As you also know, we have been investing in our manufacturing processes, because we wanted to be able to scale up in a very cost-efficient way to meet our commercial requirements. Those plans are right on track, and will mirror up, and coincide with the NDA submission. *We don’t see anything beyond those two other points* unless I’ve missed something, in which case I’ll ask Nigel [Jones] or Lesley [Russell] to weigh in. Then, I’ll turn it to Nigel [Jones] on the other question.

[...]

<Analyst> Terrific, and I really appreciate the time. Just one last question with regard to the ability to submit the data from an NDA perspective, what’s the key issue in terms of gating factor that would determine the timing for the NDA submission? Is it [INAUDIBLE], the analysis of the data, the CMC reviews What do you see as the most critical piece on that path, now, going forward?

<Defendant Russell> *I don’t think there really are any gating factors.* Obviously, we now need to write up all of the sections of the NDA with all the new clinical data, and the integrated summaries, and overall summaries. Obviously CMC components are a large part of an NDA. That’s also on track. We feel pretty good about filing the NDA at the

end of the third quarter, beginning of the fourth quarter, around that time frame. We feel that everything is on track to be able to do that.

95. Defendants Zook and Russell's statements were false because there was at least one additional gating factor – namely, that Innocoll had not raised the device issue with the FDA at all, nor obtained any waiver of the device requirement. Defendants Zook and Russell's statements thus concealed a substantial certainty that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

96. The announcement that XaraColl was all but ready for an NDA filing immediately sent Innocoll's stock price soaring from its previous close of \$7.11/share to close at \$10.51/share on May 25.

97. On June 13, 2016, filed a Preliminary Prospectus Supplement (the "Prospectus Supplement") to the F-3 Registration Statement, which provided:

After the revised guidance we received from the FDA in July 2015, we determined that we will rely upon a primary endpoint of summed pain intensity, or SPI, in our two Phase 3 trials. Based on the results of our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose compared to standard bupivacaine infiltration, we ran both Phase 3 trials in parallel, which focused only on the 300 mg dose. ***The FDA deemed our single-dose approach acceptable in our recent Type C meeting.*** Because bupivacaine is believed to work locally by blocking the generation and the conduction of nerve impulses and it is considered dose dependent, we believe a higher dose should increase the local analgesic effect. In September 2015, the first patient was dosed in both our MATRIX-1 [] and MATRIX-2 Phase 3 studies for the treatment of postoperative pain following open hernia repair with mesh using XaraColl, Innocoll's surgically implantable and bioresorbable bupivacaine-collagen matrix. ***Our MATRIX Phase 3 studies are two identical randomized, placebo-controlled, double-blinded studies to investigate the safety and efficacy of XaraColl, with pivotal data anticipated in the first half of 2016. We expect to submit an NDA for XaraColl in the second half of 2016.***

98. The Prospectus Supplement further provided:

We also initiated our Phase 3 trials for XaraColl in the third quarter of 2015, and announced top-line pivotal data in May 2016 that each study had achieved its primary endpoint as a post-operative pain relief treatment immediately following open abdominal hernia repair. ***These two pivotal Phase 3 clinical trials will form the basis of the***

evidence for efficacy for the NDA for XaraColl, which we expect to submit prior to the end of 2016.

99. The Prospectus Supplement further provided:

Develop XaraColl for treatment of post-operative pain. Based on the topline data received from our pivotal pharmacokinetic study in which we tested both a 200 mg and a 300 mg dose versus standard bupivacaine infiltration, we conducted both our Phase 3 efficacy studies with a 300 mg dose of XaraColl. ***The FDA agreed with our single-dose approach.*** We initiated our two Phase 3 efficacy studies in the third quarter of 2015. We anticipate pivotal data from these trials in the first half of 2016.

100. The Prospectus Supplement further provided:

We intend to use the net proceeds from this offering primarily to fund costs associated with our pre-commercialization activities relating to XaraColl, including through the filing ***and anticipated approval of its NDA[.]***

101. The purpose of FDA meetings is to discuss and resolve any issues that could lead to denial of approval. Therefore, by stating that they had held XaraColl Post Phase-2 and July 2015 meetings with the FDA, and that the FDA had agreed to a plan for XaraColl, Defendants conveyed that they had resolved all issues in the design of clinical trials they were aware of that could lead to denial of approval. In fact, Defendants were aware that XaraColl had device components which it was substantially certain would require separate approval from the FDA following separate clinical trials and other studies. Yet as Defendants admitted to an analyst following the end of the Class Period, Innocoll never discussed what trials and/or studies would be required for approval of XaraColl's device components with the FDA. See ¶119, below. Therefore, Defendants' statements gave the misleading impression that the FDA had deemed that all that was required for approval was for XaraColl to meet its Phase 3 clinical trial endpoints, when in fact, XaraColl would not be approvable because the FDA would require Innocoll to show that XaraColl's device components were safe and effective.

102. The filing of the Prospectus Supplement caused Innocoll's stock price to fall from \$10.95/share to \$8.85/share on June 14, 2016.

103. Just days later, on June 17, Innocoll filed a final Prospectus Supplement (the “Final Prospectus Supplement”), which made identical false statements. The Final Prospectus Supplement, however, drastically reduced the amount of the Proposed Offering, selling only 5,725,000 shares at \$7.00/share for total gross proceeds of \$40.1 million, and net proceeds to Innocoll of \$37.7 million. The underwriters were also granted an option to purchase additional shares to cover over-allotments, which they did not exercise.

104. On August 17, 2016, Defendants held a conference call to discuss Innocoll’s results for the third quarter of 2016 (the “Q3 2016 Earnings Call”). On the call, in prepared remarks, Defendant Zook acknowledged that the collagen matrix was an essential part of XaraColl:

Finally, we’re excited that the positive outcome [of XaraColl’s Phase 3 clinical trials] also provided validation for our collagen-matrix as a unique delivery platform. We believe this indicates tremendous promise for other pipeline products and we continue to expect to deliver topline Phase 3 results for one of those products, Cogenzia in the early part of the fourth quarter.

105. On November 3, 2016, Innocoll issued a press release announcing that (a) Cogenzia had failed Phase 3 trials and (b) as a result, Innocoll was abandoning Cogenzia. In the same press release, Innocoll also announced (c) that it was submitting an NDA for XaraColl:

Innocoll Announces Top-Line Data From Phase 3 Trials With COGENZIA and
NDA Submission for XARACOLL

* * *

Innocoll also announced the submission of a New Drug Application (NDA) for XARACOLL (bupivacaine HCl collagen-matrix implants) to the U.S. Food and Drug Administration (FDA) for the treatment of postsurgical pain. The submission was based upon the successful results of the MATRIX trials which showed statistically significant differences in the primary endpoint, the sum of pain intensity in both studies, as well as statistically significant reductions in opioid use and other secondary endpoints.

106. On November 4, 2016, Innocoll also held a conference to discuss both the COGENZIA results and XaraColl submission.

107. On the call, in pre-prepared responses to questions that had been posed earlier, Defendants all but guaranteed that the FDA would approve XaraColl:

<Defendant Zook>: Great. Thanks. Again, we'll open up the line for other questions relative to Cogenzia in just a moment. XaraColl, we did announce, of course, our excitement about getting the XaraColl NDA submission in, so people did ask kind of baseline your confidence in the overall NDA submission and what's the starting point? What is it that we are pursuing as our label?

<Defendant Russell>: I think I've been pretty vocal about how confident I am that XaraColl will get approved. I mean this a product that has had two very successful Phase 3 studies achieving the primary endpoint with high degree of statistical significance and really no safety issues at all. And, in fact, actually one could argue potential safety benefit and the fact that we also see a reduction in the opioid-related adverse events. ***So, this should lead to a pretty straightforward approval.***

I think people always ask then, what is the label, what will the label actually show. And that's a bit that will require some negotiation, but we have you know filed for the broadest claim of postsurgical analgesia. We have requested inclusion with 48 time points in the label both individual studies and the pooled analysis. And we've also asked some language recognizing that the use of XaraColl has reduced the influence of opioid-related adverse events. And so – and I think if we get any one of those, that's a really significant outcome for us. ***And as I've said, approval, I think, is not in question.*** It's exactly what the label may show at the end of the day.

108. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll's plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, not only had Innocoll not satisfied the device gating issue, it had not even raised the issue with the FDA. The emphasized statements thus concealed a substantial certainty that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

109. On November 22, 2016, Innocoll filed a press release with the SEC announcing Innocoll's financial and operating results for the third quarter of 2016 and providing corporate updates, stating in relevant part:

“As we recently announced, Innocoll achieved an exciting, new milestone with the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), for XARACOLL for the treatment of post-surgical pain,” said Tony Zook, Chief Executive Officer of Innocoll. ***“We anticipate an FDA acceptance of the NDA, for review, by the end of this year, and with a target Prescription Drug User Fee Act (PDUFA) action date in late August 2017, this achievement will take us another step closer to the approval and launch of XARACOLL in potentially less than one year. [...] We plan to manage our cash runway until after the anticipated XARACOLL NDA approval, expected in the third quarter of 2017, and we feel confident about our ability to finance the commercialization of XARACOLL as well as our pipeline”.***

Third Quarter 2016 and Recent Highlights

- Submitted an NDA for XARACOLL to the FDA for the treatment of postsurgical pain
 - ***FDA acceptance anticipated by the end of 2016, with a target PDUFA action date in late August 2017.***

110. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll’s plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, Innocoll had not raised the device issue with the FDA at all. Nor had it been satisfied. The emphasized statements thus concealed a substantial certainty that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl’s device component.

111. On November 22, 2016, the Company also held a conference call to discuss its third quarter of 2016 filings (the “Q3 2016 Earnings Call”). On the Q3 2016 Earnings Call, Defendant Zook represented that approval was a *fait accompli*:

First, we were very pleased to announce recently the achievement of an exciting new milestone for Innocoll. We submitted our first new drug application to the U.S. Food and Drug Administration in October for XaraColl for the treatment of post-surgical pain. We expect to hear back from the FDA by the end of this year with respect to their acceptance of the NDA filing. This would target a PDUFA action date in late August putting us on track to the approval and commercialization of a branded therapeutic in potentially less than a year.

* * *

As you can see, XARACOLL posted positive Phase 3 data back in the second quarter and we submitted an NDA for post-surgical analgesia last month. ***This is a 505(b)(2) application with a standard 10-month review and thus we anticipate being able to commercialize the product soon after an approval in Q3 of 2017.***

112. On the same conference call, Defendant Russell spoke about the XaraColl's NDA, stating in relevant part:

So, the XaraColl program, as Tony mentioned, we did submit our NDA based on our Phase 3 trial results and I'll give you some key specifics on what we asked for with respect to the potential label.

We submitted for a broad indication for single dose placement into the surgical site to produce post-surgical analgesia. We did include results of both the MATRIX-1 and MATRIX-2 trials and the pool data for the demonstration of post-surgical analgesic effect of 48 hours.

We also included language related to XaraColl's statistically significant reduction in total opioid consumption and increase in median time to first opioid use as well as the reduction in the incidences of opioid related adverse event.

We're quite confident in our CMC package and we are well-prepared for the upcoming NDA preapproval inspection. We continue to plan for medical publication and presentation of the full analysis of XaraColl's Phase 3 data, which are targeted for the second quarter of 2017.

(Emphasis added).

113. The emphasized statements misleadingly conveyed to investors that Innocoll had raised and satisfied all potential gating issues with the FDA at its pre-NDA and July 2015 meetings, and that the FDA had approved of Innocoll's plan to submit only Phase 3 trials, omitting any trials for the device portion of the XaraColl application. In fact, Innocoll had not raised the device issue with the FDA at all. Nor had it been satisfied. The emphasized statements thus concealed a substantial certainty that XaraColl would not be approved because Innocoll failed to provide evidence necessary for the approval of XaraColl's device component.

114. In prepared remarks, Defendant Zook acknowledged that the collagen matrix itself was important to XaraColl's use and functioning, stating that "[s]urgeons may have concerns about the implants and the matrix may be difficult to use."

115. But Defendant Zook also emphasized that the collagen matrix was the basis of XaraColl's appeal:

<Defendant Zook>: Yeah, <analyst name>, I think the reason, it's interesting right, for the last few years we've been spending the bulk of our time with the investor community and these were primarily the questions that seem to come up and not surprisingly they've been kind of talking points from almost a counter-detailing effort about the technology and most people just don't have access to the technology.

So for example if you have the impression and you ask an open ended question to a doctor, would you ever want to use a sponge or leave a sponge in someone, of course, the answer is no to that. ***But when the doctors actually see and feel the technology, understand that it's a collagen matrix that collapses upon itself, they have absolutely no apprehension whatsoever about using the product.***

Likewise, when you start to show them where and how the product is used as part of a surgical technique, they find it actually part of the normal surgical procedures. They are inserting meshes all the time; for them to use an implantable as part of the surgical procedure was unsolicited, something that was quite simple and easy to use and avoids the need for user knowledge on injection side and avoids the risk of intravascular injection.

And so these came up as just kind of natural talking points around the technology itself. We ask questions, we weren't as specific as, do you have concerns about using this, but I think in broad ways it came across in the in-depth interview. So we feel quite confident with the feedback we were getting.

LOSS CAUSATION

116. On December 29, 2016, Innocoll issued a press release stating that it had received a Refusal to File letter from the FDA for XaraColl. The press release stated in relevant part:

Innocoll Receives Refusal to File Letter from U.S. FDA for XARACOLL®
(bupivacaine HCl collagen-matrix implants) New Drug Application

ATHLONE, Ireland, Dec. 29, 2016 (GLOBE NEWSWIRE) -- Innocoll (NASDAQ:INNLL), a global, commercial-stage, specialty pharmaceutical company, today announced that ***it has received a Refusal to File letter from the United States Food and Drug Administration (FDA) for XARACOLL, the company's product candidate for the treatment of postsurgical pain.***

Upon preliminary review, *the FDA determined that the application, which was submitted in October 2016, was not sufficiently complete to permit a substantive review. In the Refusal to File letter, the FDA indicated among other things, that XARACOLL should be characterized as a drug/device combination, which would require that the Company submit additional information.* The company will request a Type A meeting with the FDA to respond to several issues believed to be addressable and seek clarification of what additional information, if any, will be required. Additional details will be disclosed in the future after discussions with the FDA.

“We expect to work with the FDA over the coming weeks in an effort to address the open issues and to define a path forward for a successful re-filing of our application at the earliest point in time,” said Tony Zook, CEO of Innocoll.

(Emphasis added).

117. On December 30, 2016, Innocoll’s share price fell \$1.08/share from its previous close to close at \$0.69/share, down over 61%, damaging investors.

118. On December 29, 2016, an analyst employed by JMP Securities published a report providing, in relevant part, that Innocoll’s “[m]anagement commented to us that the FDA did not raise the drug/device issue at the pre-NDA meeting.” Far from an excuse, this is in fact a grave admission. As further set out above, the purpose of a meeting with the FDA is to answer the company’s questions. Since Innocoll knew that there was a drug/device issue, it was Innocoll’s responsibility to raise the issue at the FDA meetings, rather than hoping the FDA’s inattention would allow it to obtain approval for XaraColl without conducting the device studies.

119. On March 29, 2017, Innocoll admitted that the FDA would require that Innocoll conduct “an additional short-term pharmacokinetic study and several short-term non-clinical toxicology and biocompatibility studies [as well as] additional manufacturing information.” Innocoll further announced that these studies would not be completed until the end of 2017.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

120. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Innocoll common stock during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Innocoll, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

121. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Innocoll securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds, if not thousands of members in the proposed Class.

122. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

123. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

124. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business Innocoll;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused Innocoll to issue false and misleading SEC filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and SEC filing
- whether the prices of Innocoll's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

125. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

126. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- a. Innocoll's shares and ADSs met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b. as a regulated issuer, Innocoll filed periodic public reports with the SEC;
- c. Innocoll regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press

releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- d. Innocoll was followed by at least 3 securities analysts employed by brokerage firms who wrote reports about the Company during the Class Period, including JMP Securities, Piper Jaffray, and Janney, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;
- e. On average, 0.96% of Innocoll's outstanding shares and ADSs or shares were traded weekly, permitting a strong presumption of that its shares traded on an efficient market;
- f. More than 50 market makers made a market in Innocoll's ADS; and
- g. New company-specific information was rapidly reflected in Innocoll's stock price.

127. Based on the foregoing, the market for Innocoll securities promptly digested current information regarding Innocoll from all publicly available sources and reflected such information in the prices of the shares, and Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

128. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

FIRST CLAIM
Violation of Section 10(b) of
The Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants

129. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

130. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Innocoll's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

131. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Innocoll's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

132. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Innocoll's financial well-being and prospects, as specified herein.

133. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course

of conduct as alleged herein in an effort to assure investors of Innocoll's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Innocoll and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

134. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

135. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and

for the purpose and effect of concealing Innocoll's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

136. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Innocoll's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Innocoll's securities during the Class Period at artificially high prices and were damaged thereby.

137. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Innocoll was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Innocoll securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

138. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

139. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of
The Exchange Act Against the Individual Defendants

140. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

141. The Individual Defendants acted as controlling persons of Innocoll within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

142. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to

control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

143. As set forth above, Innocoll and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: May 25, 2017

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Jacob A. Goldberg

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Attorneys for Plaintiffs

Certification and Authorization of Named Plaintiff Pursuant to Federal Securities Laws

The individual or institution listed below (the "Plaintiff") authorizes and, upon execution of the accompanying retainer agreement by The Rosen Law Firm P.A., retains The Rosen Law Firm P.A. to file an action under the federal securities laws to recover damages and to seek other relief against Innocoll Holdings plc. The Rosen Law Firm P.A. will prosecute the action on a contingent fee basis and will advance all costs and expenses. The Innocoll Holdings plc. Retention Agreement provided to the Plaintiff is incorporated by reference, upon execution by The Rosen Law Firm P.A.

First name: Gaurangkumar

Middle initial:

Last name: Patel

Address: REDACTED

City:

State:

Zip:

Country:

Facsimile:

Phone:

Email:

Plaintiff certifies that:

1. Plaintiff has reviewed the complaint and authorized its filing.
2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.
3. Plaintiff is willing to serve as a representative party on behalf of a class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff represents and warrants that he/she/it is fully authorized to enter into and execute this certification.
5. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.
6. Plaintiff has made no transaction(s) during the Class Period in the debt or equity securities that are the subject of this action except those set forth below:

Acquisitions:

Type of Security	Buy Date	# of Shares	Price per Share
Common Stock	12/29/2016	1000	1.6374
Common Stock	12/29/2016	800	1.65
Common Stock	12/30/2016	960	0.6148
Common Stock	12/30/2016	46	0.6146

Certification for Gaurangkumar Patel (cont.)

Sales:

Type of Security	Sale Date	# of Shares	Price per Share
Common Stock	01/18/2017	1000	0.73

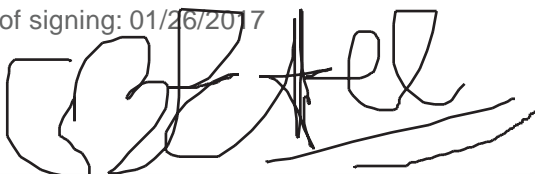
7. I have not served as a representative party on behalf of a class under the federal securities laws during the last three years, except if detailed below. []

I declare under penalty of perjury, under the laws of the United States, that the information entered is accurate: **YES**

By clicking on the button below, I intend to sign and execute this agreement and retain the Rosen Law Firm, P.A. to proceed on Plaintiff's behalf, on a contingent fee basis. **YES**

Signed pursuant to California Civil Code Section 1633.1, et seq. - and the Uniform Electronic Transactions Act as adopted by the various states and territories of the United States.

Date of signing: 01/26/2017



CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2017, I filed the foregoing *Consolidated Amended Class Action Complaint for Violation of the Federal Securities Laws* with the Clerk of Court, which will send notification of such to all CM/ECF participants, and I had all parties, to be noticed, served by electronic mail.

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